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| EXAMINER | |
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| POHNERT, STEVEN C | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/549,804 | RUSSELL ET AL. | |
| | Examiner | Art Unit | |
| | STEVEN C. POHNERT | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20,23-25 and 29-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,23-25 and 29-46* is/are rejected.

7)☒ Claim(s) *20,23-25 and 29-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

This action is in response to papers filed 1/19/2010.

Claims 1-19, 21-22, 26-28 are canceled.

Claims 20, 25, 29, 33-36, and 45-46 have been amended.

Claims 20, 23-26, 29-46 are pending.

The objection to the specification has been withdrawn in view of the amendment to the specification.

The objection to claim 21 has been withdrawn as it has been canceled.

The written description rejection has been withdrawn in view of the amendment to the claims limiting the claims to positions in SEQ ID NO 1.

The 112-2nd paragraph rejection of claims 33-34 has been withdrawn in view of the amendment.

The 102 based on Henry has been withdrawn in view of the amendment to limit the claims to the recited position in the claims, which are not taught by Henry.

The 103 based on Menges has been withdrawn in view of the amendment to limit the claims to the recited position in the claims, which are not taught by Menges.

***Priority***

The instant application was filed on 3/29/2006 as a National Stage entry of PCT/CA04/00424 filed 3/19/2003 which claims priority to US Provisional 60/4555,550 filed 3/19/2003.

***Claim Objections***

1. Claims 20, 23-25, 29-35 are objected to because of the following informalities: Claim 20 recites, "Plasminogen Activator Inhibitor-1 PAI-1." Thus the claim appears to be presenting the same name twice. The claim should be amended to indicate that PAI-1 is the abbreviation of Plasminogen Activator Inhibitor-1. It is suggested the claims be amended to recite, "Plasminogen Activator Inhibitor-1 (PAI-1)." Appropriate correction is required.

***Claim Rejections - 35 USC § 102-new Ground Necessitated by amendment***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 20, 25and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs Catalog (2000-2001 pages 26 and 42).

As noted in the MPEP 2111.02, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Accordingly, the claim language of "a kit useful for determining a genotype of a subject or subjects at a polymorphic site of Plasminogen Activator Inhibitor-1" merely sets forth the intended use

or purpose of the claimed kit, but does not limit the scope of the claims other than setting forth position 12580 of SEQ ID NO 1.

MPEP 2112.01 states, " Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established."

Although claim 20 recites, "wherein determination of said genotype results in prognosis of the subject's ability to recover from an inflammatory condition." This limitation of intended use fails to provide any structural limitation that differentiates the claimed kit from the prior art.

MPEP 2112.01 states, " Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established."

With regard to claim 25 and 29, the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

This rejection is drawn to embodiment (a) of claim 20, which requires a restriction enzyme with specificity that distinguishes alternate nucleotides at one or more of the following positions. Thus the claim requires a restriction enzyme

The NEB catalog on page 26 teaches the restriction enzyme BsmAI, which has the recognition sequence GTCTC (N)1 which encompasses position 5645 of SEQ ID NO 1.

The NEB catalog on page 42 teaches restriction enzyme HpyCH4 III, which has the recognition sequence ACNGT, which encompasses position 7434 of SEQ ID NO 1.

Thus the NEB catalog teaches restriction enzymes that distinguish one or more alternate nucleotides at position 5645 and 7434 of SEQ ID NO 1, as BsmAI and HpyCH4 III will cleave in the presence of a wildtype sequence but not if the site is mutated.

**Response to Arguments**

This is a new grounds of rejection that has been necessitated by amendment. The response asserts that the intended use of the restrictions enzymes overcome the prior art. These arguments have been thoroughly reviewed but are not considered persuasive as the claims are drawn to products and the MPEP 2112.01 states, " Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established."

The response further asserts the fact pattern of the instant case are different than in Re Ngai and that the claimed instructions overcome the prior art of record. These

arguments have been thoroughly reviewed but are not considered persuasive as MPEP 2112.01 states, " Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." The restriction enzymes of NEB thus anticipate the structural limitations of the instant claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 20, 25, 29-33, 35-38, 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henry et al (Arteriosclerosis, Thrombosis and Vascular Biology

(1998) volume 19, pages 84-91) in view GenBank Accession AF386492.2 GI:14488407 (June 19, 2001) and Chee et al (WO 95/11995).

As noted in the MPEP 2111.02, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Accordingly, the claim language of "a kit useful for determining a genotype of a subject or subjects at a polymorphic site at nucleotide position 12580 of SEQ ID NO 1" merely sets forth the intended use or purpose of the claimed kit, but does not limit the scope of the claims other than setting forth position 12580 of SEQ ID NO 1.

Although claim 20-22, 25, 29-33, 35 recites the term "kit", the claim contains no structural requirements to distinguish it from a composition, nor is the term defined to be so limited in the specification. Accordingly, the claim has been given the reasonable interpretation to encompass a composition containing the claimed molecule.

With regard to claim 25, 29, 42, 45-46, the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

With regards to claims 25,29, 41-46, the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Thus teaching of the structural elements of the kit renders the instant claims obvious.

Henry teaches PAI-1 has been implicated in insulin resistance, coronary heart disease and inflammatory status (84, 1st column). Henry teaches there is accumulating evidence that genetic control plays a role in circulating PIA-1 levels and 8 polymorphism have been identified (84, 2nd column).

Henry does not teach detection of a polymorphic site of 12219 or 12580. Henry does not teach oligonucleotides selected from SEQ ID NO 2-SEQ ID NO 11. Henry does not teach sequencing.

However, Chee et al (WO 95/11995) teaches an array of capture probes (see figure 16,and page 79 lines 23-39) and block tiling arrays (see Figure7 and page 37 line 10- page 38 line 34). Chee teaches the use of immobilized arrays to interrogate a reference sequence and its codons with a target sequence for the identification of single base mutants possible in the reference sequence can associated with disease (see page 31 lines 6-7, and page 11 line 9 and 10). Further Chee teaches this approach allows simultaneous detection and quantification of multiple target sequences (see page

32 lines18-19), allowing for sequence determination. The block-tiling array allows the interrogation of multiple nucleotide sites by use of multiple probe sets, which represent every permutation of nucleotides possible for a give sequence. Chee teaches a method of mutation detection for analyzing known target sequences for individual mutant sites and immediately adjacent bases (see page 18, lines 1-8). The tiling arrays of Chee result in sequencing by hybridization of the entire sequence of interest. Chee teaches the determination of all possible combinations of nucleotides surrounding a SNP, allowing determination of all possible nucleic acid. Chee teaches the use of capture probes of 15 to 30 nucleotides, perfectly complementary to the DNA of interrogation (see page 27 lines 2-6). Chee teaches amplification by PCR (page 61).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to examine the PAI-1 sequence taught by GenBank Accession AF386492.2 GI:14488407 in the method of Chee. The artisan would be motivated to determine identify additional mutations in the PAI-1 that could account for the alterations in PAI-1 activity associated alter PAI-1 levels including diabetes, inflammation and sepsis as Taught by Henry. The tiling array of Chee as applied to the known PAI-1 sequence taught would result in a kit containing a microarray with probes that would allow for detection of any polymorphism in the sequence by a tiling sequencing array thus rendering the instant claims obvious.

**Response to Arguments**

The response traverses the instant rejection. The response alleges claim 41 was not included in the rejection. The examiner notes that the limitation to claim 41 was

addressed in the body of the rejection and thus was rejected. The examiner has corrected the typographical errors in the statement of rejection.

The response takes issue with the reference to in re Schrieber alleging Applicant does not understand what it has to the instant rejection. This argument has been thoroughly reviewed but is not considered persuasive as the instant claims are drawn to compositions and the intended use of the instant composition do not provide any structural limitations that differentiate it from the prior art of record as the courts have held in re Schrieber.

The response alleges there is no motivation to examine any other mutations besides the 4G/5G of Henry in association with inflammatory disease. These arguments have been thoroughly reviewed but are not considered persuasive as Henry teaches "Eight different polymorphisms of the PAI-1 gene have been described so far: two (CA)n repeat polymorphisms, one in the promoter and one in intron a HindIII restriction fragment length polymorphism, and an insertion (5G)/deletion (4G) polymorphism at position -675 of the PAI-1 promoter. In addition, our group has recently identified four other polymorphisms, two G-to-A substitutions at position -844 and +9785, a T-to-G substitution at position +11053, and a deletion of nine nucleotides from a threefold repeated sequence between nucleotides +11320 and 11345." Thus contrary to the response Henry indicates there are 12 known polymorphisms and Henry's recitation of "so far," indicates that Henry believes there may be more. Thus the prior art does disclose more than a single mutation in the PAI-1 gene. The prior art discloses 12 mutations and envisions that more mutations in PAI-1.

The response then reviews the teachings of Henry and Chee noting that they do not specifically teach specifically claimed mutations. The response continues by noting the rejection states that it would have been prima facie obvious to examine the PAI-1 sequence by the method of Chee based on Henry's disclosure of the biological importance of PAI-1. The response notes that Henry teaches a correlation between the 4G/5G polymorphism and PAI-1 protein levels and deep vein thrombosis, stroke and acute myocardial infarction.

The response continues by asserting there is no indication that the claimed polymorphisms are useful for the present outcome the instant specification. These arguments have been thoroughly reviewed but are not considered persuasive as the claims are drawn to products and the MPEP 2112.01 states, " Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established."

6. Claims 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henry et al (Arteriosclerosis, Thrombosis and Vascular Biology (1998) volume 19, pages 84-91) in view GenBank Accession AF386492.2 GI:14488407 (June 19, 2001) and Chee et al (WO 95/11995). as applied to claims 20, 25, 29-33, 35-38, 40-46 above, and further in view of Wagner et al (US PG-PUB 2002/0045227, published April 18, 2002).

The teachings of Henry, Chee and GenBank Accession AF386492.2 GI:14488407 are set forth above.

The teachings of Chee suggest the amplification of a sequence to be analyzed by PCR. However, Henry, Chee and GenBank Accession AF386492.2 GI:14488407 do not teach or suggest the use of a proof reading polymerase.

However, Wagner teaches the use of a proofreading PCR as it improves the specificity of the PCR assay (0037, 10073).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of Henry, Chee and GenBank Accession AF386492.2 GI:14488407 by substituting the proofreading PCR of Wagner for the general polymerase taught by Chee. The artisan would be motivated as the substitution allows for amplification with less incorporation errors thus enabling a more specific reaction. The artisan would have a reasonable expectation of success as the artisan is merely substituting a specific polymerase in the method of Henry, Chee and GenBank Accession AF386492.2 GI:14488407.

7. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over New England Biolabs Catalog (2000-2001 pages 26 and 42) in view of Dell'Orco, Sr, et al (US Patent 5,922,852 issued July 13, 1999), GenBank Accession AF386492.2 GI:14488407 (June 19, 2001) and Buck et al (Biotechniques. 1999 Sep;27(3):528-36).

As noted in the MPEP 2111.02, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Accordingly, the claim

language of "a kit useful for determining a genotype of a subject or subjects at a polymorphic site of Plasminogen Activator Inhibitor-1" merely sets forth the intended use or purpose of the claimed kit, but does not limit the scope of the claims other than setting forth position 12580 of SEQ ID NO 1.

MPEP 2112.01 states, " Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established."

Although claim 20 recites, "wherein determination of said genotype results in prognosis of the subject's ability to recover from an inflammatory condition." This limitation of intended use fails to provide any structural limitation that differentiates the claimed kit from the prior art.

Claim 23 requires a primer or set of primers that are suitable to amplify a region flanking the polymorphic site. This broadly encompasses any primers that flank any of the sites, including primers that are at the 3' or 5' terminus.

MPEP 2112.01 states, " Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established."

The NEB catalog on page 26 teaches the restriction enzyme BsmAI, which has the recognition sequence GTCTC (N)1 which encompasses position 5645 of SEQ ID NO 1.

The NEB catalog on page 42 teaches restriction enzyme HpyCH4 III, which has the recognition sequence ACNGT, which encompasses position 7434 of SEQ ID NO 1.

Thus the NEB catalog teaches restriction enzymes that distinguish one or more alternate nucleotides at position 5645 and 7434 of SEQ ID NO 1, as BsmAI and HpyCH4 III will cleave in the presence of a wildtype sequence but not if the site is mutated.

The New England Biolabs catalog does not teach the use of primer to amplify a region flanking a polymorphic site or the use of a polymerization agent that permits nucleotide polymerization.

However, Dell'Orco et al teaches amplification by PCR for detection of mutations that result in the presence or absence of a BsmA1 restriction site in a known nucleotide sequence (column 4-column 5).

GenBank Accession AF386492.2 GI:14488407 (June 19, 2001) teaches the sequence of instant SEQ ID NO 1, which encompasses a BsmA1 restriction site.

Buck et al expressly provides evidence of the equivalence of primers. Specifically, Buck et al invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck et al also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18mer primers on the 300 base pair sequence (see page 530, column 1). When Buck et al tested each of the primers selected by the methods of the different labs, Buck et al found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No.

8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck et al expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck et al provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to design primers that flank the Bsma! Site of the accession number. The ordinary artisan would be motivated to design primers that flank the Bsma1 site because GenBank Accession AF386492.2 GI:14488407 teaches a sequence comprising a BsmA1 site. Dell'Orco teaches that Bsma1 sites were known to be amplified by PCR using a polymerase to detect mutations based on the presence or absence of a restriction site and Buck teaches any primer will amplify the nucleic acid sequence of interest. The ordinary artisan would be motivated to use an alternative primer set with a reasonable expectation of success, because Buck teaches all primers work. The claimed primers are obvious over the cited prior art, absent secondary considerations.

**Summary**

No claims are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN C. POHNERT whose telephone number is (571)272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven C Pohnert/
Primary Examiner, Art Unit 1634